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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,922	10/06/2003	Nilesh Balar	H-541	1407

7590 08/17/2005

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/678,922

Applicant(s)

BALAR ET AL.

Examiner

Humera N. Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application (PTO-152) |
| 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/06/03</u> . | 6) ☐ Other: _____ |

DETAILED ACTION

Status of the Application

Receipt of the Information Disclosure Statement filed 10/06/03 is acknowledged.

Claims 1-6 are pending. Claims 1-6 are rejected.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2 are rejected under 35 U.S.C. 102(b) as being anticipated by Shibuya (US Pat. Application Publication US 2002/0055759 A1).

The instant invention is drawn to a suture, graft or suture/graft combination having a polymer coating containing releasable biological agents for the prevention and reduction of smooth muscle cell proliferation in a sutured, grafted or injured area of a vessel or arterial wall.

Shibuya discloses a surgical suture coated with one or more biologically active compounds. Shibuya also discloses methods of making a coated suture, placing the coated suture in an organism, and methods of using the coated suture in the treatment of diseases, such as cancer (see Abstract).

Biologically active compounds that may be used include antibiotics, antifungal, antiviral, anti-microbial compounds and the like (col. 5, ¶ 0038).

Regarding the limitation 'plasma-assisted coating' claimed in instant claim 2, the plasma-assisted coating is inherent in the teachings of Shibuya, since Shibuya teaches surgical suture coatings used to deliver one or more biologically active compounds.

Claims 1-3 are rejected under 35 U.S.C. 102(e) as being anticipated by Narayanan (US Pat. No. 6,919,100 B2).

The instant invention is drawn to a suture, graft or suture/graft combination having a polymer coating containing releasable biological agents for the prevention and reduction of smooth muscle cell proliferation in a sutured, grafted or injured area of a vessel or arterial wall.

Narayanan discloses coated medical devices and a process for coating medical devices, used to treat a particular condition (see Abstract). The method comprises the steps of preparing an aqueous latex polymeric emulsion, adding at least one drug, agent and/or compound, in therapeutic dosages, to the aqueous latex polymeric emulsion for the treatment of a predetermined condition (col. 2, lines 56-62).

Medical devices that comprise the coatings include grafts, sutures, suture anchors and the like (col. 3, line 65 – col. 4, line 29).

Therapeutic agents that can be delivered through the coatings include paclitaxel, antibiotics (*i.e.*, dactinomycin), etc. (col. 4, line 30 – col. 5, line 16). Rapamycin is disclosed at column 9, lines 17-39. Rapamycin inhibits the proliferation of vascular smooth muscle cells *in vivo*. Accordingly, rapamycin may be utilized in treating intimal smooth muscle hyperplasia, restenosis and vascular occlusion in a mammal, particularly following biologically or mechanically mediated vascular injury. Rapamycin functions to inhibit smooth muscle cell proliferation and does not interfere with re-endothelialization of the vessel walls (col. 9, lines 16-28). Rapamycin also prevents T-cell proliferation when administered systemically. This is the basis for its immunosuppressive activity and its ability to prevent graft rejection (col. 9, lines 35-38). In preferred embodiments, rapamycin is incorporated onto the surface of the stent or portions thereof (col. 9, lines 51-53).

Regarding the limitation 'plasma-assisted coating' claimed in instant claim 2, the plasma-assisted coating is inherent in the teachings of Narayanan since Narayanan discloses medical devices that comprise coatings containing therapeutic substances (*i.e.*, rapamycin) to treat various diseases.

Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Mollison *et al.* (US Pat. No. 6,890,546 B2).

The instant invention is drawn to a suture, graft or suture/graft combination having a polymer coating containing releasable biological agents for the prevention and reduction of smooth muscle cell proliferation in a sutured, grafted or injured area of a vessel or arterial wall.

Mollison *et al.* disclose a medical device comprising a supporting structure having a coating on the surface thereof, the coating containing a therapeutic substance, as a drug. Supporting structures for the medical devices include arterio-venous grafts and by-pass grafts (see Abstract); (col. 4, lines 57-65).

Mollison *et al.* also disclose a method of treating a variety of disease states, including restenosis, post-transplant tissue rejection, immune and autoimmune dysfunction, fungal growth and cancer (col. 4, lines 53-56).

More particularly, the invention relates to semisynthetic analogs of rapamycin, means for their preparation, pharmaceutical compositions containing such compounds and methods of treatment employing the same (col. 1, lines 15-22).

Coatings suitable for use in the invention include polymeric coatings that can comprise any polymeric material in which the therapeutic agent is substantially soluble. The coating can be hydrophilic, hydrophobic, biodegradable or non-biodegradable. This medical device reduces restenosis in vasculature (col. 6, lines 40-49).

Hyperproliferative vascular diseases that can be treated include smooth muscle cell hyperplasia, restenosis and vascular occlusion, particularly following biologically- or mechanically-mediated vascular injury (col. 11, lines 48-53). Additionally, compounds of the

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invention possess FK-506 antagonistic properties. The compounds of the invention may be used to treat disorders involving immunodepression, including AIDS, cancer, fungal infections and trauma (including wound healing, surgery and shock) (col. 13, line 62 – col. 14, line 29).

In addition to stents, other devices used to introduce drugs to the vasculature include *grafts*, catheters and balloons (col. 11, lines 64-66).

According to Mollison *et al.*, the coating can comprise any polymeric material. The purpose of the coating is to serve as a controlled release vehicle for the therapeutic agent or as a reservoir for a therapeutic agent to be delivered at the site of a lesion (col. 12, lines 2-7).

Regarding the limitation 'plasma-assisted coating' claimed in instant claim 2, the plasma-assisted coating is inherent in the teachings of Mollison *et al.*, since Mollison *et al.* disclose medical devices comprising coatings that contain therapeutic substances used to treat various diseases.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mollison *et al.* (US Pat. No. 6,890,546 B2).

The instant invention is drawn to a suture, graft or suture/graft combination having a polymer coating containing releasable biological agents for the prevention and reduction of smooth muscle cell proliferation in a sutured, grafted or injured area of a vessel or arterial wall.

Mollison *et al.*, as delineated above, teach a medical device comprising a supporting structure having a coating on the surface thereof, the coating containing a therapeutic substance, as a drug. Supporting structures for the medical devices include arterio-venous grafts and bypass grafts (see Abstract); (col. 4, lines 57-65).

Mollison *et al.* also teach a method of treating a variety of disease states, including restenosis, post-transplant tissue rejection, immune and autoimmune dysfunction, fungal growth and cancer (col. 4, lines 53-56).

More particularly, the invention relates to semisynthetic analogs of rapamycin, means for their preparation, pharmaceutical compositions containing such compounds and methods of treatment employing the same (col. 1, lines 15-22).

Coatings suitable for use in the invention include polymeric coatings that can comprise any polymeric material in which the therapeutic agent is substantially soluble. The coating can be hydrophilic, hydrophobic, biodegradable or non-biodegradable. This medical device reduces restenosis in vasculature (col. 6, lines 40-49).

Hyperproliferative vascular diseases that can be treated include smooth muscle cell hyperplasia, restenosis and vascular occlusion, particularly following biologically- or mechanically-mediated vascular injury (col. 11, lines 48-53). Additionally, compounds of the invention possess FK-506 antagonistic properties. The compounds of the invention may be used to treat disorders involving immunodepression, including AIDS, cancer, fungal infections and trauma (including wound healing, surgery and shock) (col. 13, line 62 – col. 14, line 29).

In addition to stents, other devices used to introduce drugs to the vasculature include *grafts*, catheters and balloons (col. 11, lines 64-66).

According to Mollison *et al.*, the coating can comprise any polymeric material. The purpose of the coating is to serve as a controlled release vehicle for the therapeutic agent or as a reservoir for a therapeutic agent to be delivered at the site of a lesion (col. 12, lines 2-7).

Regarding the limitation ‘plasma-assisted coating’ claimed in instant claim 2, the plasma-assisted coating is inherent in the teachings of Mollison *et al.*, since Mollison *et al.* disclose medical devices comprising coatings that contain therapeutic substances used to treat various diseases.

Given the explicit teachings of Mollison *et al.*, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to formulate a medical device that comprises a supporting structure having a coating on the surface thereof, wherein the coating

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containing a therapeutic substance, such as a drug, with the expected result of providing an effective, beneficial and improved coated device useful for the treatment of an array of medical conditions and diseases, as similarly desired by Applicant(s).

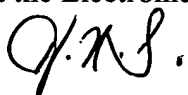
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

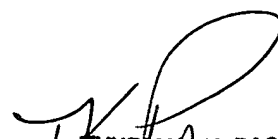
H. N. Sheikh



Patent Examiner

Art Unit 1615

August 14, 2005



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